"Community Consent" & "Problematic" Regulatory Areas

SACHRP July 15, 2008

Tissue Repositories and Consentrelated Issues

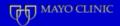
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Tissue Repositories and Consentrelated Issues

- Is "consent" the correct starting point?
- Biobanks and tissue repositories present unique challenges to human subjects protection:
 - How much "work" can informed consent do?
 - Should we rely more on "governance" and best practices?
- **™ MAYO CLUNIC** If so, how implemented?

Overview

- Moving Beyond Consent: Governance Models in Biospecimen Collections
 - (Not just waivers)
- Models of Community Engagement
 - Deliberative Democracy
- Role of Empirical Research in Policy Making
- "Leftover" Concerns



What's at Stake?



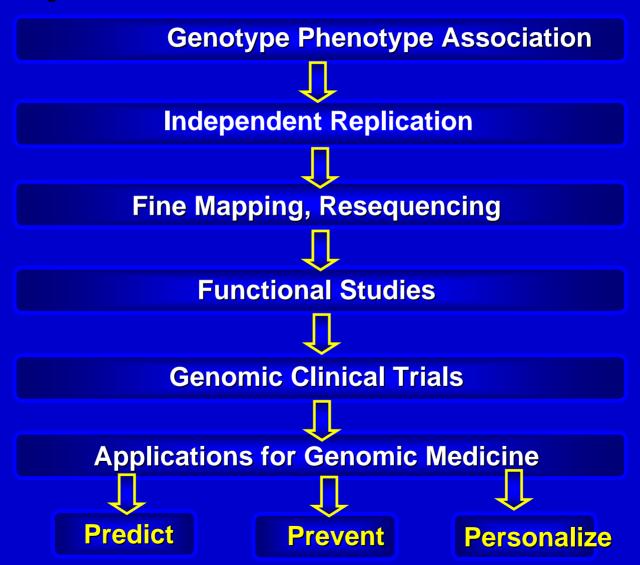
Predictive Genomic Risk Assessment: The Holy Grail of Individualized Medicine







From GWAS to personalized medicine









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GENETICS IS ABOUT TO GET PERSONAL

w don't panic, we're here to help

23andMe is a privately held company developing new ways to help you make sense of your own genetic information.

Even though your body contains trillions of copies of your genome, you've likely never read any of it. Our goal is to connect you to the 23 paired volumes of your own genetic blueprint (plus your mitochondrial DNA), bringing you personal insight into ancestry, genealogy, and inherited traits. By connecting you to others, we can also help put your genome into the larger context of human commonality and diversity.

Toward this goal, we are building on recent advances in DNA analysis technologies to enable broad, secure, and private access to trustworthy and accurate individual genetic information. Combined with educational and scientific resources with which to interpret and understand it, your genome will soon become personal in a whole new way.

To hear about new developments as they happen, sign up here:





Your genes offer a road map to optimal health

Welcome to Navigenics

We are in the midst of an exciting era of discoveries about the connections between our individual genetic composition and our personal health and wellness. These discoveries are providing a detailed map of thousands of genes that instruct the body how to grow, live and thrive — and a better understanding of how variations in these genes may influence our health over time.

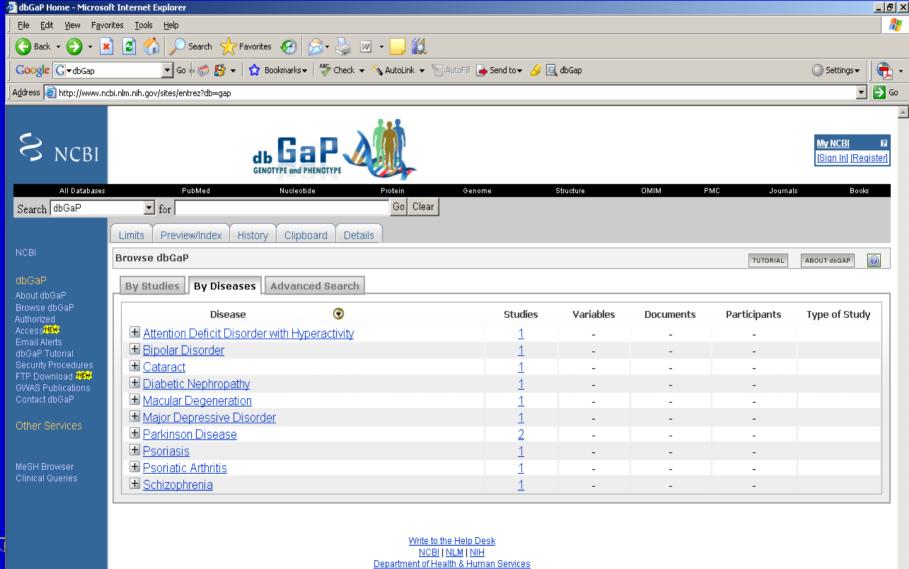
But how will you know what to do with this information and how it can help you? Navigenics will tell you your genetic health profile and help you develop a plan for wellness and prevention – so you can be even more in control of your health and live a longer, more active life.

Rapidly Changing Research Environment

- Static Regulatory Environment
 - "incrementalism"
 - Belmont
 - HIPAA



NIH Data Sharing Requirements



Privacy Statement I Freedom of Information Act I Disclaimer

Expanded Views of Research/Therapy Continuum

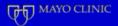
- Ancillary Care Obligations (in resource poor settings)
 - Henry Richardson, et al. PLOS
- Incidental Findings
 - Susan Wolf, et al. JLME
- Technological Change itself as a Challenge
 - DNA collection on every patient as part of personalized medicine endeavors

Returning Results

H. Greely, Annu Rev Genomics Hum Genet. 2007

 Choice not to return clinically meaningful results "...seems, at least in extreme situations, immoral, possibly illegal, and certainly unwise."

 Example: gene variant associated with high risk of colon cancer, for which early screening could be lifesaving



Planning for a new way of doing research



Lessons from the HapMap Project

- Focus on "identifiable communities"
 - Internationally & in U.S.
- "Community engagement" (not consent)
 - Considered community desires
 - Without abandonment of individual informed consent
- Does not provide a model for engaging with citizens more generally

Empirical Studies to Advance our Understanding (in process)

- Making Every Voice Count: Public Consultation on Genetics, Environment, and Health
- eMERGE Network (NHGRI "u" award mechanism)
- Expanded Network
 - CEER sites, Stanford, UNC, Duke, Baylor, etc.
- CTSA (Less developed)

"Making Every Voice Count" K. Hudson et al., Johns Hopkins "Genetics & Public Policy Center"

- Focus groups: 16 (15 focus groups plus pilot)
- Community leader interviews: 27
- National survey: 4,659
- Town halls: 5

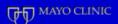


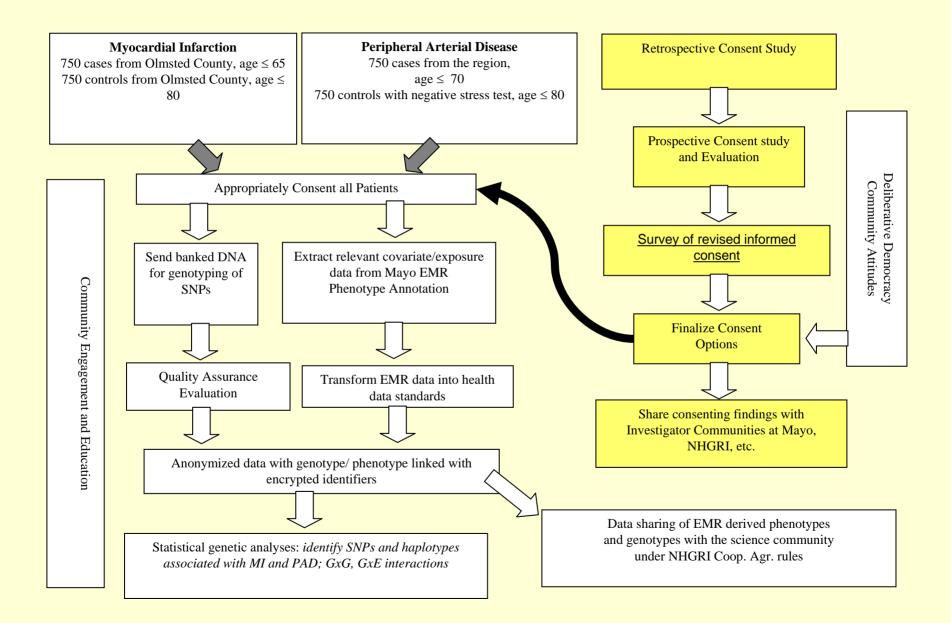
NHGRI eMERGE Consortium Electronic Medical Records and Genomics ("U" award mechanism)

- Vanderbilt (coordinating center)
- Marshfield Clinic
- Group Health/U of Washington
- Mayo Clinic
- Northwestern

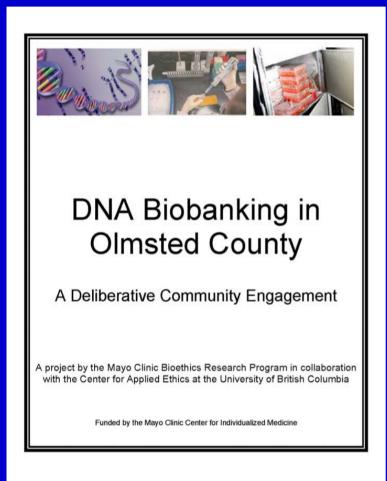


Integrating bioethics research into ongoing projects





Deliberative Democracy









What interests and values should guide biobanking? Lessons from two experiments in deliberative public consultation

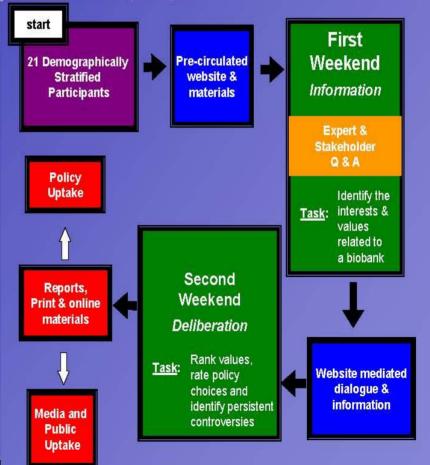
Walmsley, H.* Abadie, R.** O'Doherty, K.* Hartell, D.* Burgess, M.* Koenig, B.**

*W. Maurice Young Centre for Applied Ethics, University of British Columbia, Vancouver, British Columbia, Canada, and

**Mayo Clinic Program in Professionalism and Bioethics, Rochester, Minn.

Biobanks and Deliberative Democracy

What interests and values should guide biobanking? Existing governance frameworks were developed for small-scale research projects and are based upon personal autonomy and individual informed consent. Largescale and networked collections of biological specimens and data pose new problems. These range from the expense and unwieldy nature of the consent process for researchers, to complaints about commercialization and unauthorized use of samples by indigenous groups, to fears of data linkage by privacy advocates, and debates about the relative value of 'biobanks' versus 'cohorts' to public health. Transparent public engagement with biobanking is long overdue. We provide lessons learned from two deliberative public consultations: one conducted in British Columbia (BC), Canada, the second in Olmsted County, Minnesota (MN). A proposal for a BC-wide BioLibrary and Mayo Clinic plans for an institutional biobank provided the opportunity for citizens to shape planning for an actual, as opposed to a hypothetical, biobank. This joint project draws from theories of deliberative democracy and pioneering examples, such as the Citizen's Assembly in BC. Our aim: to facilitate a genuinely inclusive public debate. An innovative community engagement structure was developed and implemented in BC and MN. The engagement exercise included two full weekends (4 days) of face-to-face deliberation in large and small groups. Professional moderators facilitated the discussion. Diverse expert and stakeholder presentations, background readings circulated ahead of the event, and physical models of the proposed biobank features provided the stimulus for informed yet open-ended deliberation by 21 demographicallystratified citizens at each site. Recording of all sessions and online discussions and a members-only website facilitated research on the event. The challenge to the deliberants; what interests and values should guide biobanking? The challenge to the research team studying the events: what methods allow for "authentic" public consultation about complex scientific topics by citizens in a democracy?



Conclusions



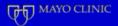
Considerations

- Genomics research elicits profound hopes, desires and social anxieties
- Need to balance scientific gains with social concerns -- not just a technical issue, but a social and political one
- Need to address these issues in an open, informed manner, engaging the community <u>before</u> implementation



A Practice with Roots in Political Theory

- Attempt to compensate for a deficit in direct participation in contemporary democracies
- Not mediated by political parties, or organized lobbies or interests, or any form of expertise
- Assumes that individual actors with divergent interests can reach a productive exchange of ideas, not merely restate entrenched positions



Deliberative Democracy Examples

- Tradition in Anglo-Saxon System
- Trial by jury (citizens' jury)
 - public works, urban renewal, ecological impacts
- Extended to inquiry into contentious issues in science and technology
 - CDC on avian flu pandemic
- British Columbia, Canada
 - Voting Methods



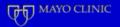
Deliberative Democracy Goals

- Goal is not just to "inform" or "educate" the community
- Seeks genuine discussion among representative community members, and,
- Make <u>non-binding</u> recommendations about implementation, governance, & long term community oversight



Summary: **Deliberative Public Consultation**

- Provides a substitute for "expert knowledge"
- Goal is not simply to let different perspectives or points of view be expressed, but,
- To make real trade-offs and compromises, encouraging the formulation of policy recommendations



Informed Consent for Biorepositories: Prospective Participants' Understanding and Opinions

Beskow LM, Dean E. Cancer Epidemiol Biomarkers Prev; in press.



Study Overview

- Funding from Duke's CTSA
- Sample: 40 individuals from Durham area
 - Over-sampled minorities & lower education levels; diversity by age & sex
- ~30 minute cognitive interview

Beskow LM, Dean E. Cancer Epidemiol Biomarkers Prev; in press



Simplifying Informed Consent for Biorepositories

Laura M. Beskow, Pl Kevin P. Weinfurt, Co-Pl



Study 1: Developing Simplified Biorepository Consent Form

Objective

 To gather data from prospective research subjects about what information they find most important to a decision about taking part in a biorepository

Design – tablet PCs

- Arm 1: Read long version of consent form and tell us what information can be eliminated
- Arm 2: Read short version of consent form and tell us what information needs to be added



Readability

Long Version (~6 pgs)

Short Version (2 pgs)

2.3 13.7 4.2

10% 70.4

6.8

Readability Statistics	Readability Statistics
Counts Words 3150 Characters 14426 Paragraphs 83 Sentences 209	Counts Words Characters Paragraphs Sentences
Averages Sentences per Paragraph 2.7 Words per Sentence 14.5 Characters per Word 4.4	Averages Sentences per Paragraph Words per Sentence Characters per Word
Readability Passive Sentences 16% Flesch Reading Ease 63.6 Flesch-Kincaid Grade Level 8.0	Readability Passive Sentences Flesch Reading Ease Flesch-Kincaid Grade Level



Large scale genomic studies linked to electronic medical records

Incorporating participant perspectives

Wylie Burke MD PhD

Department of Medical History and Ethics University of Washington, Seattle WA



CENTER FOR GENOMICS & HEALTHCARE EQUALITY

Seattle eMERGE ELSI Project (2) Consensus Process

- Year-long deliberative small group process
 - Consumers (5)
 - Researchers (3-4)
 - IRB; Group Health leadership (3-4)
- Goals
 - Develop shared understanding of
 - Potential yield of databanks / data-sharing
 - Attitudes/expectations/needs of participants
 - Achieve consensus on optimal local policies
 - Contribute to larger discussion



Goals for stewardship of biorepositories

- Appropriate uses & reporting of data
 - Researcher access
 - Publication
 - Return of results
- Data protection & oversight
 - Rapid response to errors and breaches
 - Appropriate consequences for malfeasance
- Communication about the research enterprise



"Leftover" Concerns

- Need for Harmonization with NIH GWAS policies
- Certificates of Confidentiality
 - Currently issued "study by study"
 - No provisions for ongoing biospecimen repositories set up as research resources

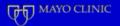


"Leftover" Concerns

- DNA as Unique Identifier
 - OHRP should consider contradictions arising from its ruling that DNA does not constitute a biological identifier under existing rules (sharing controlled by "data access committees")
- Conflicts with FOIA (DNA is excluded because personal)
- May jeopardize security

"Leftover" Concerns

- Protection from Group Harms
- Categorization of Biorepository Samples
 - Ancestry
 - "Race" (racialized groups)
 - Self-identified ethnicity
- Potential Impact on Health Disparities Research Agenda



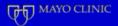
Group harm

- Not addressed in the Belmont Report or necessarily included in beneficence, respect for persons, or justice
- Should we consider 4th principle for research?
 - "Respect for communities"
 - obligation to respect values and interests of the community
 - wherever possible, protect community from harms

The International Conversation about Biobanks/Biorepositories

Further Engagement Desirable

 International Harmonization may decrease potential harms/abuse



Mark Rothstein:

"Patients will give consent and authorization to use their tissue and records, but they want to be asked."



Conclusion

- The devil is in the details.
- Exactly WHO to ask and HOW to ask is not yet fully clear.
- Role of community in developing governance and in long term oversight must be developed, nurtured, and sustained.
- Moving "beyond consent" to governance models